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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/716,146
Filing Date: November 17, 2000
Appellant(s): BOYLE, CHRISTOPHER T.

J. Peter Paredes (Reg. No. 57,364)
<u>For Appellant</u>

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 28, 2009 (including correction filed November 19, 2009) appealing from the Office action mailed February 26, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal 2007-3212, 4/30/2008 (current application 09/716,146)

Appeal 2008-1316, 9/30/2008 (related application 09/707,685)

Appeal 2008-0216, 2/21/2008 (09/783,633)

Appeal 2008-5417, 3/31/2009 (10/672,695)

Appeal 2008-1062, 12/22/2008 (10/258,087)

Copies of each of the above appeal decisions have been provided within appellants appeal brief filed September 28, 2009.

(3) Status of Claims

The statement of the status of claims (filed in correction 11/19/2009) contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,071,305	BROWN et al.	06-2000
6,938,668 B2	WHICHER et al.	09-2005

-Previous Board Decision on current application 09/716,146, mailed 4/30/2008, appeal 2007-3212- copy provided with appellants brief 9/28/2009.

-Board Decision on related application 09/707,685, mailed 9/30/2008, appeal 2008-1316- copy provided with appellants brief 9/28/2009.

-Specification of 09/443,929 (of which is incorporated by reference into the appellants current specification)-attached hereto.

-Attachment 1-marked up copy of appellants figures, attached hereto.

-Attachments 2-5-marked up copies of Brown's figures, attached hereto.

(9) Grounds of Rejection

Board Decision

The board decision mailed April 30, 2008 on the current application reversed the rejection of Brown (US 6,071,305), agreeing with the appellant that the claims require *both* the base layer and second layer of the structural elements to be made of metal, thus reversing the rejection of Brown. The examiner had previously interpreted the structural elements to only *comprise* metal, thus not necessarily requiring *both* layers to be metal (the examiner had

interpreted membrane and osmotic material 34, 44, 49, to constitute the second "layer", however these "layers" were not metal; in figures 5, 7, 8, and 10 of Brown shown in attachments to examiners answer). The board reversed Brown, by interpreting the claims to require the base and second layers to be made of metal, and as Brown's second layer (considered by the examiner previously to be 34, 44, and 49) was not metal, Brown was considered to not anticipate the claims. This is relevant since Brown has been applied herein *under a different interpretation* in which a different embodiment contains both a base and second layer *each being metal*, see below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6,071,305, cited previously) in view of Whicher et al. (US 6,938,668 B2, cited previously). Referring to claim 16, Brown discloses an endoluminal stent for delivering a bioactive agent (col.1, lines 12-20) comprising a plurality of structural elements (12; only one structural elements is shown in fig.1, 2 however a *plurality* of structural elements 12 are disclosed as additional possible embodiments at col.7, lines 34-39; mesh stent, each filament of the plurality of filaments in the mesh being a member 12), the structural elements (12's) forming a complex geometry (other configurations such as coiling stents, expandable tube stents, roving wire stents, and wire mesh stents are considered complex geometry stents; col.7,

lines 34-40) each structural element (12) having a wall thickness (cross sectional thickness of an element 12 seen in figs.3-10) and fabricated of metal (col.7, lines 11-18) comprising a base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19; or vice versa) covering the base layer (see figures 2A, 3, 6, 8 and attachments 2-5 which more clearly show location of "layers"), a void space (20) intermediate the layers and enclosed therebetween, a plurality of pores (22, 28, 54) passing through the second layer (19; or alternatively 18), such that the void space is only open through the pores (see figs.3, 6 for example), and at least one bioactive agent (23; col.5, lines 1-27).

*with respect to the term "layer": appellant's only recitation of the word "layer" is referral to a deposition *process*, in which layer upon layer is deposited until forming one unitary device (seen in appellant's figures, fig.6 shows cross-section of a structural element). The claims refer to a stent which is shown in appellants figures 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (shown in figure 7) and a round transverse cross-section (shown in fig.3 and 6-noting that figure 6 shows *two* adjacent structural elements due to the location of the cross-section). The "layers" are not clearly pointed out in the figures as the specification only refers to "layers" as depositing layer upon layer to form the device shown in the figures. It is not clear where one layer starts and ends (no demarcation lines showing discrete layers nor any reference numerals identified by "layer"), but it would *appear* appellant is referring to an abluminal and luminal "layer" (referenced as 26, 28, 33, 35 and referred to in the specification as abluminal and luminal surfaces, however since no "layers" have been pointed out in the figures, these surfaces 26, 28, 33, and 35 are the closest thing to "layers" that can be found in the figures). Brown has shown the same type of structural elements

12, each having a generally round cross-section just as appellant (figs.3-10; which also may be alternately other cross-section such as square, col.6, lines 1-5 which would provide flat planar layers instead of curved layers) with an inner void space 20. Structurally, the elements of Brown are the same as the appellants (compare fig.2a of Brown to fig.7 of appellant which each show a longitudinal cross-section; compare fig.3, 6, 8 of Brown to fig.6 of appellants, which show a radial cross-section, keeping in mind that appellants fig.6 shows two side by side structural elements; see attachments 1-5). The structural elements are the same, that is appellant and Brown show the same ***end product***. Therefore, a "layer" of appellant's structural element may also be considered a "layer" of Brown's structural element. See attachments, wherein the second layer is shown shaded to distinguish it from the base layer, both layers being part of structural element 12 which is fully made of metal, both layers are metal.

Brown discloses an endoluminal stent substantially as claimed (see above), however does not disclose vacuum deposition metal to form the structural elements (method of manufacture). Vacuum deposition is a product by process limitation (See MPEP 2113), thus patentable weight is given only to the end product, not the method of manufacture. Assuming that vacuum deposition changes the material structure of the end product, a teaching reference for creating such a material makeup may be needed. Brown is silent to mention any method of manufacture for stent 11 (only method disclosed is for embodiment in fig.17-a different embodiment-a method shown in figs.13-18; col.11, lines 62-67; which is disclosed as cutting a metal tube by laser or *other conventional cutting means*). Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques (col.3 line 52-col.4 line 30, i.e. sputtering, same type of deposition used by appellant) as an improvement over older

techniques such as cutting and etching tubes etc. (col.1, lines 31-51; cutting being the only type mentioned by Brown), in order to improve the properties of the material (discloses control of microstructure, col.2, lines 6-9; col.3, lines 18-25; also as Whicher discloses the same method of manufacture, vacuum deposition, Whicher process will inherently produce microstructure and heterogeneities, since such control over properties are characteristic of such a process). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties.

Referring to dependent claims, Brown discloses a degradable plug (biodegradable matrix 27; shown in the cavities and extending into the pores; col.8 line 62-col.9 line 5), the metals claimed (col.7, lines 12-18), bioactive agents claimed (col.5, lines 1-27), and a plurality of independent cavities (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities fig.9 for example; further, *at least one* cavity is disclosed, thus encompassing more than one, col.2, lines 59-61). The claimed controlled heterogeneities (claims 30-37) are inherent to the deposition process taught by Whicher (As Whicher discloses the same process used with the same materials as the appellant such heterogeneities are inherently controlled just as much as they are "controlled" by the appellant since appellant has admitted in the specification (incorp by ref, pgs.9-10 of 929') that the control of heterogeneities are a result of the vacuum deposition process; Whicher further discloses controlling the microstructure, see col.2, lines 15-32; col.3, lines 15-25; and Board Decision Appeal 2008-1316 of related

application 09/707,685 mailed September 30, 2008, which affirms the heterogeneities/material properties are inherent to the vacuum deposition process).

(10) Response to Argument

I.

A. The appellant has argued that Brown (US 6,071,305) is inappropriately used in a rejection since the Board decided (appeal 2007-3212) that “Brown does not describe a stent with a metal base layer and a second layer also made of metal”. In the rejection over Brown that was sent to the Board, second layer was considered by the examiner to be 34, 44, and 49 which are polymeric membranes or osmotic non-metal layers. The examiner had interpreted the claim such that the second layer did not require metal. The board however reversed this rejection based on the decision that the second layer indeed need be fabricated of metal (as is the first layer, see pg.12-13 of decision mailed April 30, 2008). Since layers 34, 44, and 49 are not metal, the rejection was reversed. It was the specific rejection of Brown that was reversed by the Board though, not the reference as a whole. Under a new and different interpretation of the Brown reference (see more details below), second layer may be considered a portion/thickness/layer of the stent strut (12), which under this interpretation, the first and second layers *are both* made of metal.

The appellant has argued that Brown does not disclose a base and second layer, and that Brown does not disclose "layers" at all. First lets examine the definition of layer. Layer is defined by its broadest reasonable definition as a thickness of a material. Brown shows a cross-section of a structural element (see any of figs.3-10) having many layers. Figure 6 for example shows horizontal demarcation lines through the structural element, each may be considered a

separate "layer" or thickness of a material. The rejection (in attachments 2-5) has provided several examples of Browns “layers”, one being the thickness 18 being one layer and thickness 19 being another layer. The appellant argued that Brown’s layers are not discrete. The examiners opinion is that “discrete” layers are *not claimed*. Further, appellants layers are not even discrete, appellants figures (cross-section of a structural element is shown in fig.6) do not shown any layer boundaries, nor do the figures show what the “base layer” and “second layer” are in the stent. The only reference to “layer” in the specification is to how the stent is manufactured, which is by depositing layer upon layer until a final unitary one-piece component results in the end product. In the end product, discrete layers are not shown. The best the examiner could interpret the disclosed "layers" to be in figure 6, would be 33, 35, which are analogous to Brown’s layers 18 and 19. Appellant’s “layers” are not shown in figures to be discrete, and if appellant’s end product is considered to have “layers”, Brown’s end product (as it has the same shape) may be also considered to have "layers". Brown's layers (18 and 19) also may be considered discrete as they are separated by void space (20). Brown’s layer 18 and layer 19 are each portions or thicknesses or layers of the structural element 12. Appellant argues that mere portions or thicknesses of strut 12 may not be considered a layer. The examiner disagrees. Reference numerals or recitations of the term “layer” are not required by Brown to enable layers. The figures alone provide support for layers. This is exactly how appellant’s layers are considered. Appellant’s layers 33, 35 are portions or thickness of the structural element 31. The end products of appellant and Brown are the same.

The appellant has argued that Brown's layers are not discrete layers. However, discrete layers are not claimed. Further Brown's layers seem to be as "discrete" as appellants layers are (since even appellant's layers are not shown to be discrete-fig.6 shows not layer boundaries).

The appellant has argued that a portion or thickness of a structural element may not be considered a "layer". The examiner disagrees, as the broadest reasonable definition of the term layer is a thickness of a material. Thus any thickness of Brown's structural element may be considered a "layer". As appellant point out, figure 6 of Brown has demarcation lines indicating different section of the structural elements. It is the examiners opinion that one section or a grouping of adjacent sections may be considered a "layer" as such is a thickness of the structural element.

The appellant has argued that a "layer" may not have a circular, oval, elliptical or octagonal shape. The examiner disagrees. A layer is a thickness and could be flat or curved. Brown shows a cross-section of a structural element in fig.6 for example, one layer 18 is a thickness of half or less than half of the structural element, thus has a semi-circular or curved form. A layer bent into a curved shape does not preclude it from being considered a "layer". In fact, even in appellant's figure 6, the layers are curved. It is noted also that Brown discloses various other cross-sectional shapes for the structural elements, including square (col.6, lines 1-5), which in this instance would provide a bottom, top and two side layers, all being flat planar layers; the bottom layer would be considered the base layer and top layer would be considered the second layer.

The appellant has argued that examiner only refers to figure 6 of appellant's specification for comparison, and none of the other figures which show different embodiments. This is

because the claims refer to a cylindrical stent made up of a plurality of structural elements forming a complex geometry. Figures 1 and 8-10 do not show such an embodiment. The only figures supported by the claims are figures 2-7. Figures 2 and 5 show plan/isometric views of the entire stent made up of the plurality of structural elements. Figures 4 and 7 show a longitudinal cross-section showing a single structural element lengthwise (side-view). Figures 3 and 6 show a radial cross-section of a single (and in fig.6-double) structural element end-view. Thus, the cross-sections of appellant's figure 3 and 6 are the end-view or cross-section that is analogous to the cross-sections taken in Brown's figures 3-10. Further, the cross-sections shown in appellant's figures 4 and 7 are analogous to the cross-sections of Brown's fig.2A. The other figures simply do not apply as they do not support the claimed subject matter. Appellant's specification discloses that each (thus all, including the embodiments of figs.2-7) of the disclosed embodiment may be made by vacuum deposition or forming/braiding tubing following by laser cutting or etching. The only figures that show the claimed invention are figures 2-7 and that is why these figures are referred to in the rejection and used for comparison purposes against Brown.

See attachments 2-5 for interpretation of Brown's embodiments and what the examiner is considering the base and second layers. See attachment 1 for appellants figures used for comparison.

It is also noted that appellant repetitively refers to the "helical stent" of Brown. The helical stent seen in figure 1 and 2 is however not the embodiment used in the rejection. Brown shows a helical stent made up of one structural element (12) would helically into a cylinder and forming the stent (the radial cross-section of one structural element is seen in figs.3-10 and the

longitudinal cross-section of one structural element seen in fig.2a). Brown *additionally* discloses alternate stent embodiments such as coiling stents, expandable tube stents, roving wire stents, and wire mesh stents (these embodiments are that used in the current rejection), the elongated member (strut 12) being the filaments or fibers forming the disclosed stents (col.7, lines 33-40). These alternate stent embodiments are the stents used in the rejection. Thus, although these embodiments are not shown, it is clear that complex stent geometries are disclosed made up of a *plurality* of structural elements 12, each individual structural element 12 of the complex stent having the same cross-section as seen in figs.3-10. Figures 3-10 show the cross-section of a *single* structural element (strut) and *not* the cross-section of the entire stent.

B. The appellant has argued that Brown does not disclose a void space intermediate the base and second layers. The examiner disagrees. Base and second layers are shown in the attachments 2-5 provided herein. Further, Brown is considered by the examiner to contain a void space (cavity 20) intermediate the two layers (18, 19; see attachments 2-5). The appellant argues Brown's void space is not enclosed and point to fig.2a. The examiner disagrees. Void (20) is completely enclosed by the layers (18, 19, which are the luminal and abluminal layers). The openings shown in fig.2a are at the most proximal and distal *ends* (not sides) of the structural element. Figure 2a shows a continuous void (cavity 20), however *discontinuous* voids are also disclosed (thus the ends would be closed off in this instance, not open as seen in fig.2a; need not extend entire length, col.5, lines 50-55). Either way, layers 18 and 19 do enclose the void, see figure 6 of Brown. The appellant argues that Brown's void is not "intermediate" the layers, since it is not centered in the middle of the structural element. The examiner disagrees. The void is

not required to be centered, it is only required to be positioned in between the base and second layer, which Brown's void (20) is. Intermediate is defined as positioned in between two points, not in the middle or centered as appellant has inferred.

C. The appellant has argued that Brown is not combinable with Whicher, since the examiner has provided no reason that Whicher is combinable with Brown (no reason that vacuum deposition would be combinable with the stent of Brown). The examiner disagrees. Brown does not disclose any methods of manufacture of the stent structural elements of figures 3-10 and disclosed mesh stent of col.7, lines 33-40. Brown briefly discloses one way to make a stent according to a different embodiment (figs.13-18; col.11, lines 62-67) which it is unclear if this method also applies to the embodiment used in the rejection, however since it is the only method disclosed, it may be assumed it applies. Brown discloses making stents by laser cutting or *other conventional methods*. Brown discloses laser cutting the structural elements and then laser cut or etching the cavities/void space. Thus Brown acknowledges other methods not disclosed are feasible (does not teach away from alternative methods of manufacture). Whicher teaches in the same field of complex geometry stents (col.6, lines 45-53), vacuum deposition as an alternate method, in fact an improvement over the methods disclosed by Brown, *for the purpose of increased control of material properties, thus providing a stent with optimal material properties* (col.2, lines 6-9; col.3, lines 18-25; see rejection)-this is the reason for combining. Vacuum deposition of Whicher may be used to deposit the metal to form the structural elements of Brown. The pores and cavities may later be formed by laser drilling, etching, etc, after the deposition. Only the structural elements (metal present in the end product) are required to be

"vacuum deposited". Whicher and Brown both are within the same field of vascular stents made of the same materials (stainless steel, platinum, gold, titanium, and alloys thereof, etc) thus are combinable. It is noted that even appellant's specification notes that either braiding and laser cutting/etching may be used or alternately, vacuum deposition (pg.10-11), thus appellant evidences that one is an obvious alternative to the other.

D. The appellant has argued that Brown and Whicher would not have provided a predictable construct (final product), that is that Whicher does not disclose the process parameters during vacuum deposition that the appellant uses and Whicher does not disclose how to create a stent with voids. The examiner disagrees. Particular process parameters (temperature, pressure, etc) have not been claimed, thus are not required by Whicher. Further, the claims only require the end product (stent) to be vacuum deposited. Vacuum deposition is a product by process limitation. See MPEP 2113. Since the claims are product claims, patentable weight is given to the *end product only*, not its method of manufacture (vacuum deposition). Whicher is used as a teaching reference for vacuum deposition assuming that such a process alters the material microstructure of the end product as Whicher teaches. As appellant's specification (929' incorp by reference) admits, it is known and standard vacuum deposition processes that are used with the invention (no specific parameters are disclosed to make the method special or different), thus the fact that Whicher teaches vacuum deposition on stents is enough. The appellant argues Whicher does not teach the exact stent structure of Brown or how to make the stent of Brown, however this is not required. Whicher is used *only* as a teaching of method of manufacture (how to configure the metal). Brown discloses all structural features of

the claim with regards to the stent configuration. Brown discloses braiding wires and welding them together or laser cutting a tube to form the stent, then, after forming the stent structural elements, cavities may be formed in the elements by further cutting. Whicher teaches vacuum deposition is an obvious alternative to braiding/welding wires and laser cutting tubes (these are methods disclosed by Brown). Whicher teaches making complex stent geometries (fig.2, 3; col.6, lines 21-53; including use of patterns, masks, release layers, multiple metal layers etc, fig.6b, col.7 line 57-col.9, lines 65 wherein multiple layers are disclosed to be deposited which may be subjected to machining after deposition-thus the cavities may be cut out after deposition, leaving a stent whose structural elements are vacuum deposited), thus encompassing and within the realm of Browns stent. It is noted that even appellant's specification notes that either braiding wires and welding them together, or laser cutting tubes may be used or alternately, vacuum deposition (pg.10-11), thus appellant evidences that one is an obvious alternative to the other. Appellant argues that pores and voids MUST be formed during deposition, but this is not true as appellant's specification discloses alternate means for forming such pores and voids (welding tubes together). Further, a solid stent may be vacuum deposited and then the pores/voids formed *after* deposition (by laser cutting or etching out the pores). The claims do not require the pores/voids to be formed by deposition (even if they did, this would be a product by process limitation and irrelevant). Thus if Brown's stent configuration (mesh stent) were made by vacuum deposition of metal as taught by Whicher (instead of braiding and welding wires or laser cutting a tube), Brown's stent would be of vacuum deposited metal. Even if Brown's pores/cavities in the structural elements were formed by laser cutting them out or

etching them out after deposition, the metal of Brown's structural elements would still be considered "vacuum deposited".

II.

The appellant has argued that Brown does not disclose a degradable plug (claim 20). The examiner disagrees. Active agent 23 may be carried in a delivery matrix 27 which is a degradable polymer, as the polymer degrades, active agent is released out of the pores, and as the matrix 27 degrades, particles/pieces of the matrix 27 break apart and move through the pores to exit the stent. Delivery matrix is only shown in fig.4 (shown within pore), but seemingly may apply to cavities of all shown embodiments of the structural elements 12. Also, some of the active agents 23 are themselves degradable (collagen, elastin, etc. col.5, lines 1-27) and are shown located in the pores (fig.3, 9, and 10), thus themselves may be considered a degradable plug, as multiple active agents in combination are disclosed.

III.

The appellant has not argued claims 26-27 separately. The examiners comments under I above apply here as well.

IV.

The appellant has argued that Brown does not disclose the void space to comprise a plurality of independent cavities along the length of the structural elements (claim 28). The examiner disagrees. Each structural element making up the disclosed mesh stent of Brown

(struts 12 of stent disclosed col.7, lines 34-40) may have its own single cavity, thus making up a plurality of cavities amongst the plurality of structural elements; alternately, one embodiment shows a single structural element (12; fig.9) having two parallel cavities that are independent; alternately, Brown discloses a structural element (12) to comprise *at least one* cavity (col.2, lines 59-61), thus encompassing more than one cavity per structural element. The appellant argues that the figure 9 interpretation is incorrect, as the two cavities 20 in figure 9 are not free from control or restraint from one another thus may not be considered independent. The examiner disagrees. Cavities free from control or restraint from one another is not claimed, nor is it supported by appellant's specification. Such a feature also is not required by the term "independent" cavity. Independent cavity has been interpreted to be separate, distinct and individual *positioning*.

V.

A, B, C. The appellant has argued that Brown in combination with Whicher does not disclose a stent with a surface having controlled heterogeneities thereon, that controlled heterogeneities are not inherent to the vacuum deposition process, and that Whicher does not enable the deposition process to control heterogeneities. The examiner disagrees.

First, controlled heterogeneities in not recited in the appellants specification, however is supported by an incorporation by reference to application 09/443,929 (incorporated at pg.11 of current specification) of which the vacuum deposition process is incorporated. Appellant has claimed the heterogeneities to consist of grain size, grain phase, grain material composition, surface topography (supported by pg.8 of 929'). These properties are admitted in the 929' to be

inherently present and inherently controlled and optimized by the vacuum deposition process (see pg.9-10 of 929' vacuum deposition "*yields* a metal having controlled heterogeneities", the vacuum deposition suitable for use being those *known and standard* in the microelectronics art, "the foregoing properties are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics..and coating arts").

The appellant argued that Whicher does not disclose (regarding claim 30) controlled heterogeneities thereupon. The examiner disagrees. Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col.2, lines 6-10, 16-31; col.3, lines 17-25, controls composition, surface roughness, microstructure). See also Board decision (Appeal 2008-1316) for related application 09/707,685 mailed on September 30, 2008 (common inventor, same assignee and same attorney of record) in which the Whicher reference was affirmed based on similar claim language. Whicher's method of vacuum deposition (i.e. sputtering, the same technique used by appellant; col.3, lines 51-60) inherently control's the stents heterogeneities, because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the appellant. Appellants disclose in their specification that it is the vacuum deposition process that controls the heterogeneities. Since Whicher is using the same process as the appellant, Whicher is inherently "controlling heterogeneities" just as much as the appellant is.

Whicher teaches a method of manufacturing an endoluminal stent (100) having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example) made by vacuum deposition (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which

are the same type of vacuum deposition processes used by the appellant, are disclosed by Whicher, col.3 lines 51-60). The appellant's specification (incorporated 929') admits that it is the use of vacuum deposition that controls heterogeneities (see above). Thus, since Whicher uses vacuum deposition (sputtering for example) just as the appellant uses vacuum deposition (sputtering), Whicher's stent will posses the controlled heterogeneities that the appellant's stent possesses inherently.

Further, Whicher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties (col.3, lines 17-25), therefore, inherently the heterogeneities are controlled, since grain size, grain phase, grain material composition, and surface topography are elements of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whicher discloses *selection* of a process *condition*. Whicher discloses selection of a temperature, pressure, and rate during deposition (see examples), therefore, inherently the precipitates are being controlled, since amount, size, and form of the grains and surface topography are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which appellant has disclosed to be the method of controlling heterogeneities), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled the grain size, phase, material composition, etc. Because Whicher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Specific numerical sizes for the grains has not been claimed, the only thing claim is that the grains be *controlled*. By selection of process

conditions (temp, pressure, rate of deposition), the heterogeneities (material properties such as grain size, grain phase, etc) are considered to be *controlled*.

Also, every metal has a specific granular makeup (for example titanium has a different granular makeup than gold) and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Overall, it is the examiner's position that Brown discloses the same end product mechanical structure as the appellant (compare fig.3 or 6 of appellants to fig.6 of Brown; each showing a radial cross section of a structural element having a top layer, bottom layer and void space therebetween). Brown discloses all structural features of the claimed invention, however does not disclose the method of manufacture (vacuum deposition-product by process limitation). Brown laser cuts a tube to form the structural elements (prior to forming cavities) and Whicher teaches vacuum deposition is an obvious alternative and improved method of laser cutting tubes, in order to provide a stent whose material has optimal properties (created and inherent by the deposition). It would have been obvious to use Whicher's method of deposition to make the stent structural elements of Brown-noting that the voids/pores may be laser drilled later, after the deposition of the metal. Thus is created a stent with vacuum deposited metal. Alternately, Whicher teaches use of multiple layers of metal deposited and incorporating release layers, patterns, and masks, thus the stent of Brown, including pores and cavities, is envisioned and capable of being made by the method of Whicher.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in appellants Appeal Brief filed September 28, 2009.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Cheryl Miller/

Examiner, Art Unit 3738

Conferees:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775